Cancer Clinical Trials Advisory Council
Meeting Minutes
October 28, 2011

Council members present in person: **Ron Dewsnup**, Allegiance Benefit Plan Management; **Sharon DeJongh**, Bozeman Deaconess Cancer Center; **Paul Burns**, Cancer Patient; **Jo Duszkiewicz**, Billings Clinic; **Cory Hartman**, New West Health Services; **Dr. Jack Hensold**, Bozeman Deaconess Cancer Center; **Brendan Steele**, Cancer Patient; **Diane Ruff**, Associated Employers Group Benefit Plan & Trust; **Russ Hill**, DOA-Health Care and Benefits Administration; **Dr. Ben Marchello**, Frontier Cancer Center and Montana Cancer Consortium

Council members present on the phone: **Kristin Page Nei**, American Cancer Society Cancer Action Network; **Marian Diaz**, Symetra Life Insurance Company; **Dr. Grant Harrer**, Benefis Health System; **Rachel Peura for Monica Berner**, BCBS of MT; **Dr. Robert Geller**, Billings Clinic

Council members absent: **Paul Bogumill**, Mountain West Benefits; **Cori Cook,** EBMS; **Michael Foster**, Catholic Hospitals

Council chair Kristin Page Nei called the meeting to order at 1:05 and reviewed the agenda. **Ron Dewsnup moved to approve the minutes and Dr. Ben Marchello seconded the motion. They were approved unanimously.**

Discussion on Draft Causes of Denials

The group examined the "Causes of Denials" document consisting of statements staff had gleaned from the discussion at the previous meeting. Clarification was given that the statements were not decisions by the Council or researched findings/facts, but rather perceptions of what the causes were. The study calls for the Council to examine the causes so that we can clarify reasons for denials and suggest solutions to the issues.

Staff of CSI reported the response to each of the cause statements received in the on-line survey put out to the council prior to the meeting. Twelve of 18 members responded to the statements. (The statements with their percentages are on-line here, but no official action was taken)

There was considerable discussion on #4 and the relationship between clinical trials, the four phases, and standard of care in oncology. A suggestion was made that clinical trials be referred to as a best available option, rather than THE standard of care. Agreement was not reached.

Payers pointed out that the real cause of denials is because most plans do not cover items that are considered investigational or experimental. Definitions of clinical trials from both health care organizations and patient advocacy organizations use language that supports the idea that trials are experimental. Employers wondered why they should have to pay for something that is still considered experimental.

Providers reiterated that they are only asking payers to cover routine treatment that other cancer patients get; the sponsor will be covering the experimental component. Payers stated that everything related to the trial would still be considered experimental or investigational. The payers do not have any way to differentiate between the investigational and non-investigational components. Payers need to have as much information on the trials as possible up front if we want to see a more standardized approach.

Providers stated that even the information that they provide now is not reviewed quickly enough and patients do not have enough time to wait. A payer stated that the process is very cumbersome and health plans are not easily interpreted; also health care administrators may not have enough information. A suggestion was made that the council establish a suggested package of information administrators need to provide to the payer.

The chair suggested that we agree to set aside this discussion and address the causes of denial document at a later date, at which time we will focus first on identifying causes and solutions together. A suggestion was made to categorize the causes into issues that can be resolved through education and ones that won't likely have easy solutions. A payer recommended adding details to the definition of qualifying routine cost, administration of therapy, and fleshing out specific goals. She elaborated that insurers and employers may not understand the differences between trials in various phases and this may cause them not to consider coverage of trials in certain phases.

A provider identified what he understood to be two major issues going on – concern about the excess cost involved with the trial and having to pay for complications. He believes the issues can be addressed with data and suggested that Dr. Marchello take time in the next meeting to go over specifics in data to address the concerns.

Dr. Marchello agreed to provide written information on the general process of clinical trials from their creation from national medical standards, though testing, to redefining the standard of care, as well as a description of trials in different phases.

The Council decided that agreement on definitions was more important than debating the causes and may add clarity to the discussion and lead to possible solutions more easily. **The discussion of "causes for denials" was set aside indefinitely.**

<u>Public Comment</u>

Amber Ireland of the Montana Municipal Interlocal Authority, self-funded insurance pool came to show her support for the work the council is doing. She has been following our efforts and is willing to help out in any way possible. She stated that she understands that there is often more to the story than the red tape delays. She stated that it can be difficult knowing what can and can't be covered in a plan.

<u>Definitions of Routine Care</u>

The Council moved on to discussion of the definitions for routine care. CSI staff laid out key differences between four proposed definitions: the 2007 proposal, the EBMS Proposal, Medicare and the ACA.

2007 and EBMS

Those who supported this starting point suggested that the EBMS proposal updated and streamlined the 2007 proposal and we should not look back. Much of the EBMS proposal comes from a recent Oregon agreement. The following elements were discussed:

- This is the only definition of the four that uses the term "medically necessary." It is not defined by the ACA or Medicare and gives full discretion to payers.
- The proposal does not require coverage for adverse affects of trials. The only way this would be resolved would be through the required independent medical review under the ACA.
- "Deviations from protocol" language is very broad and could render all trials ineligible for coverage because of very minor deviations. If the intention is to exclude "off label" trials, it needs to be restated.
- The propsals excludes phase 1 trials completely. The ACA and Medicare cover routine care during all phases. Payers pointed out that Medicare has the ability to limit the amount of the payment and private payers do not. They expressed concern that trial sponsors would back away from payment for Phase 1 trials if they knew payers were required to cover these without limits.

Medicare

- Includes the cost of delivering the new agent.
- Covers complications
- Defines trials, not by phases, but by saying it must have a therapeutic intent

ACA

- Very clearly states that all phases are to be covered.
- Is the logical starting point since that is where we are headed by law.
- Is very likely to rely on the Medicare definition

After considerable debate, **Cory Hartman made a motion to start with the ACA definition of routine care costs. Russ Hill seconded the motion which passed with three dissenting votes**-Ron Dewsnup, Grant Harrer, and Diane Ruff. Members clarified that it was only a starting place and elements of the other definitions would be considered for inclusion or exclusion.

The Council also agreed it would not consider the definition of routine care in isolation from the definition of clinical trials and would work to reach agreement on all definitions mentioned in the ACA.

The Council reviewed the ACA language and **agreed to accept the definition of Routine Patient Costs under ACA Sec. 2709 (a) (2) with a addition of a 4th exclusion: (iv)"items or services customarily provided by a clinical trial sponsor."** Clarification was made that because complications were not expressly excluded, they were part of the care covered under the inclusion.

They also agreed to accept the provisions in (a)(3) and (4) on "in-network" and "out-of-network" providers and the full definition of "qualified individuals" in (b).

An inclusive motion was made by Ron Dewsnup and seconded by Russ Hill and was passed unanimously to accept the highlighted language below for part of Montana's definition, with the understanding that we would address to rest of the document:

AFFORDABLE CARE ACT H.R. 3590, MARCH 23, 2010
SEC. 2709. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

''(a) COVERAGE.—

''(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

''(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

''(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

''(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

''(2) ROUTINE PATIENT COSTS.—

''(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

''(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—
''(i) the investigational item, device, or service, itself;
''(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or
''(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
"(iv) items or services customarily provided by a clinical trial sponsor

''(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

''(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

''(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

''(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

‘‘(2) Either—

‘‘(A) the referring health care professional is a participating health care provider and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or ‘

‘(B) the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

‘‘(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan’s (or coverage’s) health care provider network unless out-of network benefits are otherwise provided under the plan (or coverage).

‘‘(d) APPROVED CLINICAL TRIAL DEFINED.—

‘‘(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

‘‘(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

‘‘(i) The National Institutes of Health.

‘‘(ii) The Centers for Disease Control and Prevention.

‘‘(iii) The Agency for Health Care Research and Quality.

‘‘(iv) The Centers for Medicare & Medicaid Services.

‘‘(v) cooperative group or center of any of the entities described in clauses (i)through (iv) or the Department of Defense or the Department of Veterans Affairs.

‘‘(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

‘‘(vii) Any of the following if the conditions described in paragraph (2) are met:

‘‘(I) The Department of Veterans Affairs.

‘‘(II) The Department of Defense.

‘‘(III) The Department of Energy.

‘‘(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

‘‘(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

‘‘(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

‘‘(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

‘‘(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

‘‘(e) LIFE-THREATENING CONDITION DEFINED.—In this section, the term ‘life-threatening condition’ means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

‘‘(f) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.

The next meeting was set for Tuesday, December 13th via videoconference. Staff was instructed to set up videoconferencing sites in Billings, Bozeman, Missoula, Helena, and Great Falls.

The meeting was adjourned at 3:56pm.